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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,901	03/19/2001	Jeffrey A. Hubbell	262/304US	1025

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EXAMINER

BERMAN, SUSAN W

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 01/18/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,901

Applicant(s)

HUBBELL ET AL.

Examiner

Susan W Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

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Drawings

The drawings are objected to because (1) Figures 2B, 4, 6, 7A, 7B, 11a, 11b, 12A, 12B, 13 are not labeled to indicate what is shown in the graphs (2) Figures 14a, 14b and 14c on page 13/13 are not clearly printed (3) Figure 3 should be on a separate sheet instead of being between Figures 2a and 2B. The words and numbers cannot be read. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required.

A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) because there are numerous pages with marks that sometimes make the disclosure unclear and there are numerous line outs, as mentioned above. See page 1, line 15, page 2, line 5, and pages 6-9; see pages 9-25 and 27-67, lines 23-25 each page; see page 68, line 6, page 70, lines 10 and 13, and page 71, lines 3 and 4. Pages 68-71 include a list of references that should be listed on PTOL Form -1449 as prior art. The disclosure contains citations to the references listed on pages 68-71 but does not provide a clear indication of which reference is referred to. It is suggested that the references listed on pages 68-71 should be numbered and that the numbers should appear in the specification as superscripts to clearly indicate what listed reference corresponds with the citation. A brief description of the drawings is a required part of the specification that are missing in the specification as filed.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute

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specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fukui et al (4,195,129). See the Abstract and the Examples.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,700,848). See the Abstract and Examples 16-18.

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Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaetsu et al (4,321,117) in view of Fukui et al. Kaetsu et al disclose a method comprising contacting polymerizable monomers with a physiologically active substance, making the monomers into a specific shape and irradiating the shaped article with light or an ionizing radiation. See Example 8. Kaetsu et al disclose that the solution can be irradiated with light or ionizing radiation, thereby disclosing that light irradiation can be used in an equivalent manner to the gamma radiation used in Example 8. However, Kaetsu et al do not mention adding photoinitiators to the aqueous solution.

The disclosure of Fukui et al is discussed above. Fukui et al employ a photoinitiator and ultraviolet light for polymerizing analogous compositions comprising a polymerizable monomer and an active biological substance. It would have been obvious to one skilled in the art to employ light irradiation instead of ionizing radiation in the method disclosed by Kaetsu et al, as taught by Kaetsu et al. It would further have been obvious to one skilled in the art to employ a photoinitiator in the method taught by Kaetsu et al when using light irradiation, as taught by Fukui et al in analogous art. The function of a photoinitiator in methods of polymerizing using light irradiation is well known in the art. One of ordinary skill in the art at the time of the invention would have been motivated to employ a photoinitiator, as taught by Fukui et al, by an expectation of enhancing the speed of polymerization using light irradiation.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Berman whose telephone number is (703) 308-0040.

The fax number for this group is (703) 872-9310 or, for submissions after Final Rejection, (703) 872-9311.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist at telephone number (703) 308-0661.

S B
January 10, 2002



Susan Berman
Primary Examiner
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